REMARKS

Applicants have amended the claims to include reference to the deposit accession numbers for each of the claimed bacterial strains. Each of the strains (*Streptococcus cristatus* List40-13, and *Lactobacillus salivarius* strains Salm-9, List40-18 and List40-41) were deposited with an International Depository Authority (American Type Culture Collection) as established under the Budapest Treaty on the International Recognition of the Deposit of Microorganisms for the Purposes of Patent Procedure, and assigned accession numbers PTA-6310, PTA-6307, PTA-6308 and PTA-6309, respectively. The biological material was deposited on November 16, 2004, and represents the biological strains specifically identified in the specification as strains List40-13, Salm-9, List40-18 and List40-41. Access to the deposit will be made available during the pendency of the patent application and all restrictions imposed by the depositor regarding availability of the deposited material will be irrevocably removed upon granting of the patent subject to the exception allowed under 37 CFR 1.808(b). In addition, claim 7 has been further amended to specify that the composition includes at least two of the listed strains.

Claims 1, 7-17, 19-23, 25-27 and 29-30 stand rejected under 35 USC § 112, first paragraph for lack of enablement. In response, applicants have amended to the claims to include the specific accession numbers for the biological deposits of each strain. As stated above, the deposits were made under the terms of the Budapest Treaty and each of the deposited strains will be irrevocably and without restriction or condition released to the public upon issuance of a the patent, subject to the exception allowed under 37 CFR 1.808(b).

Applicants respectfully submit they have fully complied with the biological deposit requirements of 37 CFR 1.801-1.809, and respectfully request the withdrawal of the rejection under 35 USC 112, first paragraph.

Claims 1, 7-17, 19-23, 25-27 and 29-30 stand rejected under 35 USC § 102(a) as being anticipated by, or in the alternative, under 35 USC § 103(a) as obvious over Stern et al (US Patent no. 7,132,102). Applicants respectfully traverse this rejection.

First of all applicants note that claims 8-13, 15, 16, 19-23 and 27 all require the presence or use of the bacterium *Streptococcus cristatus* List40-13, in conjunction with a *Lactobacillus salivarius* strain. Stern et al fails to teach or suggest a composition comprising a *Streptococcus cristatus* strain and a *Lactobacillus salivarius* strain. Furthermore, applicants respectfully submit that the *Lactobacillus salivarius* strain disclosed by Stern et al is a different strain from applicants' claimed *Lactobacillus salivarius* strains, and therefore Stern also fails to anticipate claims 1, 7, 14, 17, 24, 25, 26, 29 and 30.

In support of applicants' statement that the claimed strains of *Lactobacillus salivarius* are different from the strain disclosed by Stern et al, applicants submit herewith a Declaration Under 37 CFR 1.132 with accompanying data. In particular, genomic DNA was recovered from each of the claimed strains of *Lactobacillus salivarius* as well as the Stern et al *Lactobacillus salivarius* strain. The genomic DNA was cleaved using the *Apa*I restriction endonuclease and the restricted DNA was subjected to pulse - field gel electrophoresis (PFGE). Staining of the resultant gel revealed that restricted genomic DNA from each of the tested *Lactobacillus salivarius* strains produced a distinct banding pattern (See Exhibit A). Based on this data each of the *Lactobacillus salivarius* strains (Salm-9, List40-18, and List40-41) described in the present application represent separate and distinct *Lactobacillus salivarius* strains relative to the one disclosed by Stern et al (United States Department of Agricultural, Agricultural Research Service Patent Culture Collection Accession Number NRRL-B30514). In addition each of the three *Lactobacillus salivarius* strains (Salm-9, List40-18 and List40-41) is also a separate and distinct strain relative to one another.

Applicants respectfully submit the data provided in Exhibit A established that the claimed *Lactobacillus salivarius* strains are **not** identical to the strain disclosed by Stern et al, and therefore Stern et al fails to anticipate the presently claimed invention. Accordingly, applicants respectfully request the withdrawal of the rejection of claims 1, 7-17, 19-23, 25-27 and 29-30 as being anticipated by Stern et al.

With regards to the rejection of claims 1, 7-17, 19-23, 25-27 and 29-30 as being obvious over Stern et al (US Patent no. 7,132,102), applicants respectfully submit the Examiner is overstating the teaching of the Stern reference. Stern et al provides a general disclosure that strains of *Lactobacillus* or *Enterococcus* may have utility in reducing levels of colonization by a target bacterium (such as *Salmonella* and *Campylobacter*). However, the mere fact that a claimed species or subgenus is encompassed by a prior art genus is not sufficient by itself to establish a prima facie case of obviousness. *In re Baird*, 16 F.3d 380, 382, 29 USPQ2d 1550, 1552 (Fed. Cir. 1994). Applicants' claimed invention is narrowly tailored to claim specific organisms that applicants have discovered exhibit desirable characteristics. These specific claimed bacteria cannot be derived from the strain disclosed by Stern simply because there is insufficient knowledge of the structural differences between the relevant strains. The data provided in Exhibit A demonstrates that each of the relevant stains is structurally different from the other, but the detail of those differences is unknown.

The Examiner states that if the claimed species are different from the one disclosed by Stern et al, "then such difference is considered to be so slight as to render the claims obvious..." Applicants respectively submit that the Examiner's statement is whole unsupported by the record. The Data of Exhibit A shows each of the strains exhibit very distinct restriction patterns when the genomic DNA is cleaved with *Apa I*. Thus we know on a gross level that these strains have differences in their genomic DNA sequences. But the record is devoid of any evidence as to whether these nucleic acid sequence differences are "slight". On the contrary, given the fact that combinations of the individual isolated strains proved more effective in reducing Salmonella populations than use of one strain alone (see Table 7 and accompanying text on page 18, line 15 through page 19, line 20) implies that the individual strains complement one another. Such an effect would not be seen if the differences between the various claimed *Lactobacillus salivarius* strains (Salm-9, List40-18 and List40-41) were "slight" or inconsequential.

Applicants also note that Stern et al relied on a biological deposit to enable their disclosed strain. Applicants also relied on deposited materials in accordance with 37

CFR 1.801-1.809 to enable the claimed invention. Due to the lack of a complete characterization of the relevant bacterial strains, applicants respectfully submit that one of ordinary skill would be incapable of modifying the strain disclosed by Stern et al to create the presently claimed strains. Furthermore, due to the highly unpredictable nature of the field (which relies on isolating bacteria from natural intestinal bacterial populations), one would not have a reasonable expectation that the claimed strains could be independently isolated using the procedures disclosed in Stern et al. Again, this is why the biological deposit rules exist, to allow those skilled in the art to be able to reproducibly make and use the claimed biological materials. Therefore, applicants respectfully submit that due to the unpredictable nature of the field, one of ordinary skill in the art would not have a reasonable expectation of successfully isolating the identical strains that applicants have, and now claim as their invention.

In addition, applicants note that Stern et al is devoid of any teaching or suggestion that two or more strains of *Lactobacillus salivarius* could be used to reduce the population of *Salmonella* and *Campylobacter* and that such a combination would enhance the effectiveness of the composition. As the Examiner has noted, it is surprising that different strains of the same bacterial species of *Lactobacillus salivarius* could complement each other to provide an enhanced efficacy in inhibiting growth of *Salmonella* and/or *Campylobacter*. However, as indicated in Table 7 and the accompanying text on page 18, line 15 through page 19, line 20, the individually isolated *Lactobacillus salivarius* **do** complement each other to enhance the overall effectiveness in preventing the growth of *Salmonella* and/or *Campylobacter*.

Even further removed form the teachings of Stern et al, applicants note that claims 8-13, 15, 16, 19-23 and 27 all require the presence or use of the bacterium *Streptococcus cristatus* List40-13 in conjunction with a *Lactobacillus salivarius* strain. Stern et al fails to teach or suggest the use of a *Streptococcus cristatus* strain either alone or in combination with other bacterial strains to reduce populations of *Salmonella* and/or *Campylobacter*.

Accordingly, applicants respectfully submit Stern et al fails to enable or suggest applicants' unique compositions, which they have found to be surprisingly efficacious in

inhibiting the growth of *Salmonella* and/or *Campylobacter*. Accordingly, applicants respectfully requests the withdrawal of the rejection of claims 1, 7-17, 19-23, 25-27 and 29-30 as being anticipated by or, in the alternative, as obvious over Stern et al.

Applicants believed the claims are in condition for allowance and respectfully request passage of the application to issuance. If the Examiner has any questions or comments such that a conversation would speed prosecution of this application, the Examiner is invited to call the undersigned at (434) 220-2866.

Respectfully submitted,

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